202324

RSPA-1993-13541-93

November 18, 1994

Edward Mazzullo
Office of Hazardous Material Standards
Department of Transportation
400 7th Street S.W.
Washington, DC 20590

Dear Mr. Mazzullo,

As per my conversation today with Jennifer Antonnelli, I wish to petition for an exemption from the 49CFR, Part 72, requirements for transportation of infectious/potentially infectious waste.

Our company is involved in the manufacture and distribution of patient support surfaces to prevent and heal pressure ulcers. Through our service centers and liaisons with local homecare dealers, we provide these systems to patients regardless of their environment: institution or home. Any of these patients might have Hepatitis B, AIDS, or other potentially infectious diseases.

The patient contaminated systems on rental would be picked up, transported to a location for decontamination, then reprocessed for use by another patient. The transportation might include, depending upon location, via car, van or shipped via common carrier (e.g. UPS). The contaminated mattresses are placed into a plastic bag and sealed, then placed into a shipping carton. The pumps and air tubing are placed into a shipping carton. Company cleaning policy recommends the removal of gross contaminants (e.g. blood, urine, feces, etc.) prior to packing for shipping.

I have attached a position paper which highlights why I believe that our products should be exempt from compliance to the rigorous procedures outlined in 49CFR, Part 72. Our company wants to be in full compliance with the intent of the regulation to protect the public health, however, I believe that as written, the regulation is too stringent for the minimal potential public health risk that our patient contaminated systems hold.

I welcome the opportunity to discuss this further with you, and please do not hesitate to contact me with any questions. My thanks in advance for your consideration.

Very truly yours,

Audrey Witko
Compliance Manager

CC: J. Britton, L. Nass

Formerly Huntleigh Healthcare
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HNE HEALTHCARE

TRANSPORTATION OF PATIENT CONTAMINATED PRODUCT

OVERVIEW

Federal regulations are in place to protect the public health from contamination of etiologic agents and other biologicals. These may be found in the Code of Federal Regulations, Section 42, Part 72. The spirit of this regulation involves quantities of etiological agents which, if exposed, poses a threat to the public health. Therefore, in order to protect the public, certain biologic agents are forbidden to be transported within the United States, while others must comply with strict packaging and labelling requirements.

An 'etiologic agent' is described as a viable microorganism or its toxin which causes, or may cause, human disease. In its broadest sense, therefore, patient contaminants would fall under this category.

The shipping requirements of etiologic agents (according to 42 CFR Part 72) in volumes not exceeding 50 ml mandates that a watertight tube or vial be used as a primary container (refer to Attachment A). The primary container would then be wrapped in absorbent material and placed into a secondary container. Both the primary and secondary containers would then be placed in an outer shipping carton for transportation. A biohazard label is required on the outer carton.

Clearly, the intent of this regulation is to guard against interstate shipment of ***large quantities*** of potentially dangerous bacteriological substances. The amount of potential contaminatination on patient soiled product is miniscule in comparison.

INFECTIOUS WASTE

This is taken verbatim from document "307104 *Infectious Waste* from the Centers for Disease Control & Prevention (Atlanta) :

> There is no epidemiologic evidence to suggest that most hospital waste is any more infective than residential waste. Moreover, there is no epidemiological evidence that current hospital waste disposal practices have caused disease in the community. Therefore, identifying wastes for which special precautions are necessary is largely a matter of judgment about the relative risk of disease transmission. Hospital wastes for which special precautions appear prudent are microbiology laboratory waste, pathology waste, bulk blood or blood products and sharp items such as needle or scalpel blades. In general, these items should either be incinerated or decontaminated prior to disposal in a sanitary landfill. Bulk blood,

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suctioned fluids, excretions, and secretions may be carefully poured down a drain connected to a sanitary sewer. Sanitary sewers may also be used to dispose of other infectious wastes capable of being ground or flushed into a sewer.

Please refer to your particular state or local health department for information about laws on waste disposal in your own area.

It is evident that the greatest risk is present where there is a large volume of potential contaminants (e.g. bulk blood, pathology specimens, etc.). Again, this supports the premise that the amount of contaminants that may be present on a patient contaminated product will pose no serious health risk regarding transportation.

CENTERS FOR DISEASE CONTROL & PREVENTION (ATLANTA)

Since 1971, the authority for governing the interstate shipment of etiological agents was delegated to the CDC&P. Advice has been taken from the Biosafety Branch, Office of Health & Safety, Centers for Disease Control & Prevention (Atlanta) regarding the transportation of patient contaminated product. Lynn Myers, Biosafety Branch, recommended a 'common sense' approach to this situation. Although, at worse case senario, a patient contaminated product could harbor potentially infectious microorganisms, the likelihood of transmission of disease in this manner would be minimal. She suggested that the contaminated product be placed in an impervious bag, sealed with a tie wrap, and placed into a sturdy shipping carton.

PRODUCT DECONTAMINATION

HNE Heatlhcare recommends that, prior to shipping, product be cleaned of any gross contamination (blood, feces, urine, other body fluids) prior to shipping. Contact HNE Healthcare for recommended cleaning solutions and procedures.

FOR FURTHER INFORMATION

Contact Audrey Witko, Compliance Manager, HNE Healthcare, 227 Route 33 East, Manalapan, New Jersey 07726, phone 1-800-223-1218, extension 127.

REFERENCES

Publications

1. 42 CFR, Part 72 - Interstate Shipment of Etiologic Agents
2. Packing and Shipping Instructions (Centers for Disease Control & Prevention)
3. Bloodbourne Disease Transmission (Centers for Disease Control & Prevention)
4. Infectious Waste - Non-HIV (Centers for Disease Control & Prevention)
5. Infectious Waste - HIV (Centers for Disease Control & Prevention)
6. Disinfection and Sterilization Practices (Centers for Disease Control & Prevention)
7. Chemical Germicides - EPA Classification (Centers for Disease Control & Prevention)
8. Guide for Shipping Ground and Air Hazardous Materials (United Parcel Service of America, Inc., 1993)

Discussions with Various Agencies

1. US Department of Health & Human Services - Public Health Services
2. Centers for Disease Control & Prevention
3. NJ Department of Health
4. NJ Department of Transportation
5. United Parcel Service (UPS)

PACKAGING AND LABELING OF ETIOLOGIC AGENTS

FIGURE 1

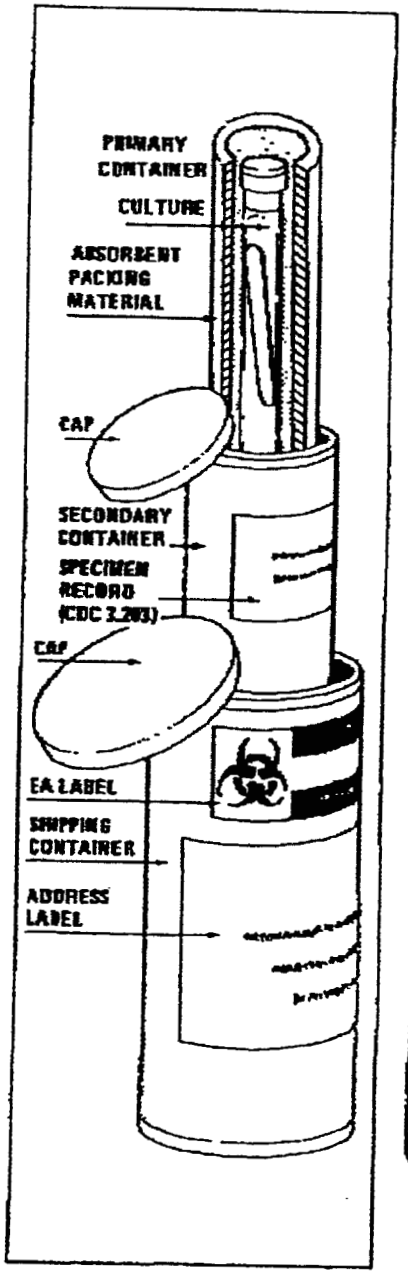
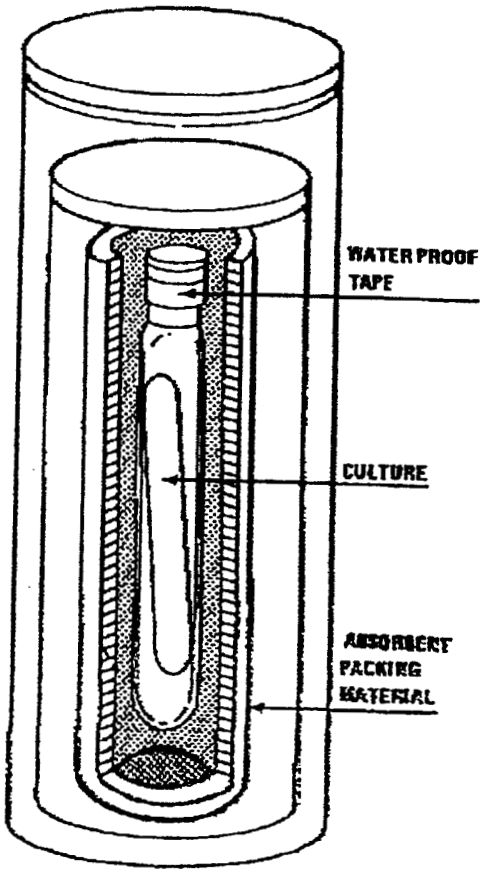


FIGURE 2



CROSS SECTION OF PROPER PACKING

The Interstate Shipment of Etiologic Agents (42 CFR, Part 72) was revised July 21, 1980 to provide for packaging and labeling requirements for etiologic agents and certain other materials shipped in interstate traffic.

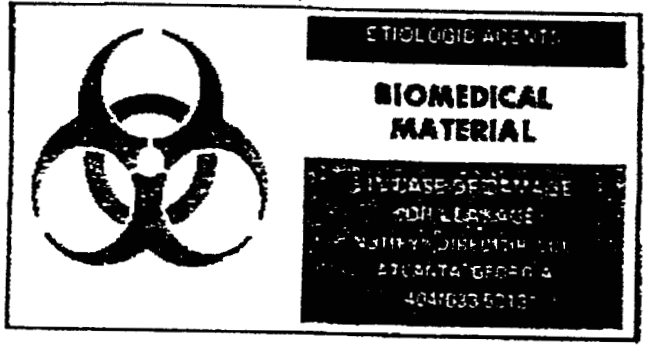
Figures 1 and 2 diagram the packaging and labeling of etiologic agents in volumes of less than 50 ml. in accordance with the provisions of subparagraph 72.3 (a) of the cited regulation. Figure illustrates the color and size of the label, described in subparagraph 72.3 (d) (1 - 5) of the regulations, which shall be affixed to all shipments of etiologic agents.

For further information on any provision of this regulation contact:

Centers for Disease Control
Attn: Office of Biosafety
1600 Clifton Road
Atlanta, Georgia 30333

Telephone: 404-639-3883
FTS-236-3883

FIGURE 3 (Red on White)



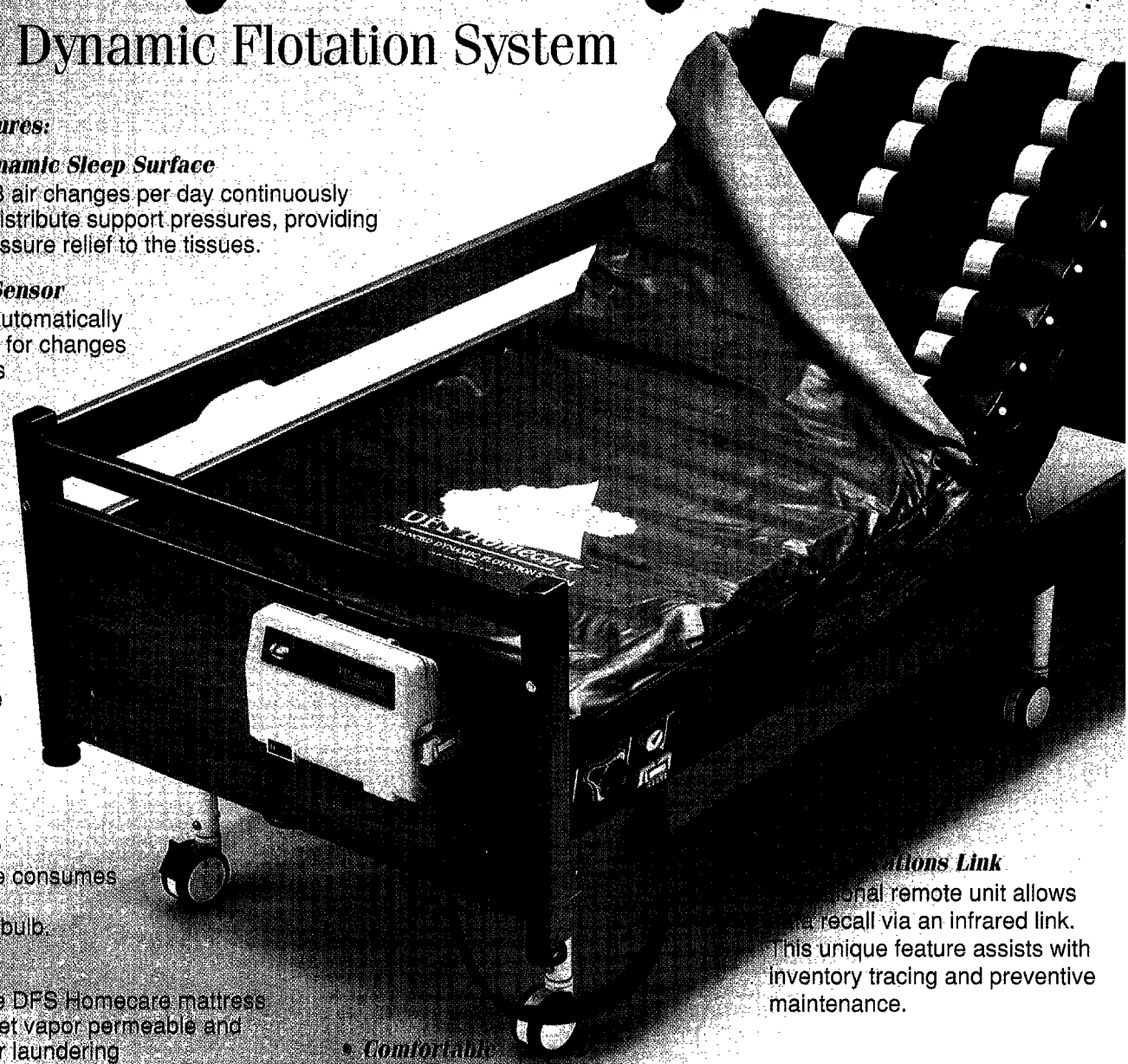
DFS® HOMECARE

Advanced Dynamic Flotation System

The DFS Homecare from HNE Healthcare is a technologically advanced pressure relieving mattress system designed specifically for patients in the home or long term care environment.

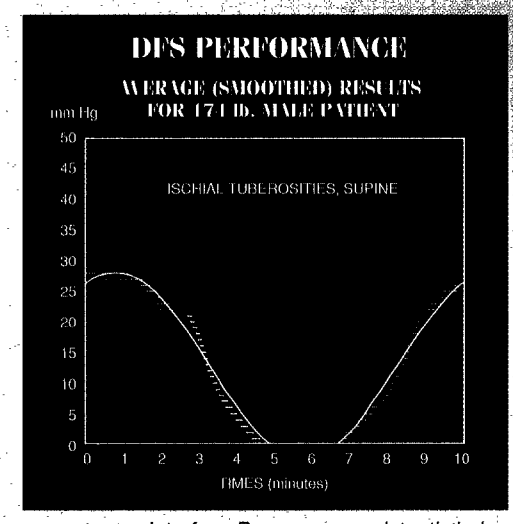
DFS® Homecare from HNE Healthcare

Advanced Dynamic Flotation System



Features:

- ***Dynamic Sleep Surface***
  288 air changes per day continuously redistribute support pressures, providing pressure relief to the tissues.
- ***Auto Matt® Sensor***
  The system automatically compensates for changes in the patients position. No manual adjustment is required by the patient or caregiver.
- ***"Power Loss" Protection***
  The unique "transport" mode provides a pressure reducing support surface for up to 12 hrs. following a power failure.
- ***Economical to Use***
  The DFS Homecare consumes less electricity than a 25 watt light bulb.
- ***Easy to Clean***
  The top cover of the DFS Homecare mattress is water resistant, yet vapor permeable and may be removed for laundering
- ***...ations Link***
  ...onal remote unit allows ... recall via an infrared link. This unique feature assists with inventory tracing and preventive maintenance.
- ***Comfortable***
  The mattress is compatible with most types of bedframes and will conform to any position.



Interface Pressures consistently below capillary closure pressure. Test Data available on request.

Technical Description:

Pump (Including Hanging Bracket)		**Mattress** (Including Tubeset)	
Reorder No.	DFS–H–2000	Reorder No.	DFS–H–2082
Length	13"	Length	82"
Height	8"	Height	8"
Weight	7½ lbs.	Width	32"
Power	110v/25 watts	Weight	22 lbs.
Cycle	10 min.		
Electrical safety stds.	UL544 • IEC601-1 • BS5724, part 1 • VDE0750, teil 1		

For information on the full line of HNE products including pressure relieving devices, compression systems and fetal/vascular Dopplers, please call 1-800-223-1218.

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